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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,543	05/26/2000	Beatrice Gaugler	LUD 5353.5 (10016355)	7364

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/579,543	GAUGLER ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 1, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-58,60,61 and 63-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-58,60,61 and 63-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 38-58, 60, 61 and 63-66 are pending.

Claims 38-41, 43, 44, 58 and 60 have been amended.

Claims 38-58, 60, 61 and 63-66 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections

Claim Objections

3. Claim 58, line 2 is no longer objected to because the following informality listed in the Paper mailed May 25, 2004, paragraph 4 has been corrected.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38-58, 60, 61 and 63-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claims 38-41, 43, 44 and 60 have been amended to list discrete nucleotides of SEQ ID NO: 13, SEQ ID NO: 14 and SEQ ID NO: 15. These claims now recite specific nucleotides 1129-1155 of SEQ ID NO: 13, nucleotides 1129-1155 of SEQ ID NO: 14 and nucleotides 224-250 of SEQ ID NO: 15. Applicants have not pointedly express wherein the specification support is for these discrete nucleotides of the listed sequences in the context of the newly amended claims. The Remarks filed June 1, 2004 direct the Examiner to U.S. Patent number 5,405,940 (issued April 11, 1995). The Examiner has reviewed this patent and evidences the nucleotide sequences, however the instant specification does not contemplate an isolated nucleic acid molecule or cDNA molecule which encodes a tumor rejection antigen, wherein the complementary sequence of said molecules hybridizes fully to the newly added discrete nucleotide sequences of SEQ ID NO: 13-15. Furthermore, it is not clear why Applicants are relying on patent '940. In the instant case nucleotides 224-250 of SEQ ID NO: 15 are not identical to the sequences of SEQ ID NO: 15 listed on page 1 of patent '940. In addition, not only are the discrete nucleotides not supported by the instant application, but also the Applicants appear to establish a new subgenus. Applicants' reliance on generic disclosure and possibly a single or limited species do/does not provide sufficient direction and guidance to the "features" currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically

described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Applicants should pointedly express by page and line number where in the specification support can be found the amendments or delete the new matter.

6. The rejection of claims 38-58, 60, 61 and 63-66 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants assert that the rejection set forth in the Paper mailed May 25, 2004, page 2, paragraph 6 "...makes no sense" and while "[t]he art relied upon shows that ...one method may have failed, another worked. Hence, the sequence can be distinguished, one from the other. Furthermore, Applicants assert the claims now require a specific sequence and PCR can distinguish the molecules. In conclusion Applicants assert the claims require a sequence unique to the MAGE-4 family and satisfy the written description requirement. These arguments and points of view have been carefully considered, but found unpersuasive.

It remains that the written description in this case only sets forth SEQ ID NO: 13 (gene for MAGE-4), 14 (gene for MAGE-41) and SEQ ID NO: 15 (cDNA for MAGE-4)

and not specific nucleotides listed in the claims which also address:

(a) polynucleotides which encode a tumor rejection antigen precursor and a part of a tumor rejection antigen precursor, wherein the complementary sequence of said isolated nucleic acid molecule hybridizes to the nucleic sequence set forth in SEQ ID NO: 13, 14 or 15 and fragments of the said sequences;

(b) polynucleotides, as well as cDNA molecules which encode a fragment (including those processed by a cell) of tumor rejection antigen precursor, wherein the complementary sequence of said isolated nucleic acid molecule hybridizes to the nucleotide sequence set forth in SEQ ID NO: 13, 14 or 15 and fragments of the said sequences;

(c) polynucleotides which encode a tumor rejection antigen, wherein the complementary sequence of said isolated nucleic acid molecule hybridizes to the nucleic sequence set forth in SEQ ID NO: 13, 14 or 15; and

(d) isolated DNA molecules which encode a MAGE-4 or MAGE-41 tumor rejection antigen precursor comprising fragments of SEQ ID NO: 13, 14 or 15, as well as the vectors and host cells that contain all of the said polynucleotides of (a)-(b). The specification does not provide sufficient written description of MAGE tumor antigen precursors as broadly claimed. The broad claims are based upon the limited disclosure/recitation of a limited number of nucleic acids encoding a specific MAGE-4 or MAGE-41. There is insufficient written description of the structural attributes that define or distinguish a MAGE tumor rejection antigen precursor, including MAGE-4 and MAGE-41 tumor rejection antigen precursors from one another or other molecules.

However, it is noted that the structure (e.g. sequences) of MAGE molecules differ from one another and that such MAGE molecules are classified as separate molecules (e.g. MAGE-4 and MAGE-41).

The specification continues not to provide sufficient written description of a tumor antigen precursor based upon the limited disclosure/recitation of a one nucleic acid encoding each different MAGE tumor antigen precursor. There is insufficient written description of the structure / sequences of nucleic acids or complementary sequences of which hybridize to SEQ ID NO: 13, 14 or 15 and encode a MAGE tumor antigen precursor and, in turn, provide the appropriate structural and functional attributes of a MAGE tumor antigen precursor. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Only nucleic acids defined as SEQ. ID. NO: 13, 14 and 15 consisting of specific nucleic acid residues, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. For the reasons of record and set forth in the Paper mailed May 25, 2004 the rejection is maintained.

7. The rejection of claims 38-58, 60, 61 and 63-66 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid sequences

identified as MAGE-4 (SEQ ID NO: 13 and 15) and MAGE-41 (SEQ ID NO: 14), does not reasonably provide enablement for any isolated nucleic acid molecule which encodes a tumor rejection antigen, precursor or a fragment thereof, wherein the complementary sequence of said isolated nucleic acid hybridizes to a nucleotide sequence set forth as SEQ ID NO: 13, 14 or 15 is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants traverse the instant rejection in the same manner presented above in paragraph 6. Moreover, Applicants assert that the rejection set forth in the Paper mailed May 25, 2004 on page 9, paragraph 7 does not discuss MAGE-4 or MAGE-41 and accordingly is irrelevant to the pending claims. These arguments and points of view have been considered but found unpersuasive.

There is insufficient guidance and direction as to how to make and use the breadth of MAGE tumor rejection antigen precursors encoded by nucleic acids that hybridize to SEQ ID NO: 13, 14 or 15; other than MAGE-4 and MAGE-41 encoded by SEQ D NO: 13, 14 and 15 in the absence of structural or functional attributes that define a MAGE tumor rejection antigen precursor.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using tumor antigen precursors encoded by nucleic acids of which the complementary sequence hybridizes to SEQ ID NO: 13, 14 or 15, wherein the appropriate structural and functional features of a MAGE tumor antigen precursor (e.g. MAGE) would be maintained would be

unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. For the reasons of record and set forth in the Paper mailed May 25, 2004 the rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
9/7/2004

Alana M. Harris, Ph.D.
07 September 2004